Citation:

Chien YC, Liu JF, Huang YJ, Hsu CS, Chao JC. Alcohol levels in Chinese lactating mothers after consumption of alcoholic diet during postpartum "doing-the-month" ritual. *Alcohol.* 2005; 37 (3): 143-150.

PubMed ID: 16713502

Study Design:

Non-randomized trial

Class:

C - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the effects of exposure to ethanol through cultural practices by lactating mothers.

Inclusion Criteria:

Healthy, non-smoking, pregnant Chinese women enrolled before delivery.

Exclusion Criteria:

Not described.

Description of Study Protocol:

Recruitment

Twenty-three healthy, non-smoking, pregnant Chinese women were recruited prior to delivery from gynecology and obstetrics clinics at Taipei Medical University Wan-Fang Hospital (Taipei, Taiwan).

Design

Non-randomized trial.

Dietary Intake/Dietary Assessment Methodology

Three-day dietary records.

Blinding Used

Lab tests were used to analyze the alcohol levels.

Statistical Analysis

- Summary statistics were expressed as mean±SD.
- Concentration–time profiles of ethanol in blood and milk were plotted for average levels, as well as for each subject
- Differences in time to peak and peak levels between blood and milk alcohol concentrations were analyzed using a non-parametric Wilcoxon signed-rank test
- $P<0.05$ was considered statistically significant
- The areas under the concentration–time curve for milk (AUCm) were determined via a linear trapezoidal method
- Correlations between blood and milk alcohol levels for each subject were determined using linear regression analysis
- Alcohol doses potentially available to infants were estimated on the basis of total milk yielded in 30 minutes and the highest alcohol levels in mother's milk with complete absorption assumed
- Time required for the milk alcohol level to return to zero level was estimated using linear least-square extrapolation based on descending phase data
- The ethanol disappearance rate was obtained from the slope of the regression line.

Data Collection Summary:

Timing of Measurements

- Subjects were asked to refrain from imbibing alcohol for three days prior to the experiment to ensure a low baseline alcohol level
- On the morning of the study, each subject was weighed, blood sample was taken and milk from each breast was emptied with an electric breast pump [the alcohol levels were used as baseline levels (time zero)]
- After the subjects consumed chicken soup flavored with sesame oil and rice wine (CSSR), milk samples (2.0ml) were obtained from each subject at 10, 20, 30, 40, 60 and 90 minutes using an electric breast pump
- At 120 minutes post–CSSR exposure, milk was emptied from both breasts using electric breast pumps
- Venous blood samples (2.0ml) were obtained using an in-dwelling catheter before alcohol dosing and at 20, 40, 60, 90 and 150 minutes after subjects consumed CSSR.

Dependent Variables

- Alcohol level in milk: Analyzed using a gas chromatograph (GC) equipped with a flame ionization detector (Model 6890, Hewlett Packard Inc., DE, USA). One microliter of sample was injected directly into the GC. A capillary column (Part CP-WAX 52CB, 30 mX0.53mm internal diameter, one um thickness; Varian Chrompack Inc., CA, USA) with nitrogen as the carrier gas running at 6.0ml per minute
- Blood (serum) alcohol levels: Analyzed using a commercial test kit (Vitros ALC Slides, Ortho-Clinical Diagnostics,
  Inc., NY, USA). Ethanol concentration in each sample was determined by measuring the increase in NADH (reduced form of nicotinamide adenine dinucleotide) concentration at 340nm after a five-minute incubation at 37 centidegree.

Independent Variables

Alcohol levels in CSSR: Analyzed using a gas chromatograph (GC) equipped with a flame ionization detector (Model 6890, Hewlett Packard Inc., DE, USA).

Description of Actual Data Sample:

- *Initial N:* 23 women
- *Attrition (final N):* 23 women
- *Age:* Lactating mothers
- *Ethnicity:* Chinese
- *Location:* Taipei, Taiwan.

Summary of Results:

- Mothers' blood alcohol levels peaked at 20 minutes after ingestion of CSSR and decreased almost linearly to zero level (i.e., zero-order kinetics) after three hours
- Milk alcohol levels peaked at around 20 to 40 minutes and decreased linearly thereafter. At 135 minutes post-CSSR consumption, alcohol concentrations in milk were 9.0±5.2mg per dL, significantly higher than the pre–CSSR consumption level
- The mean time required for milk alcohol levels to return to zero level was estimated at about 175 minutes based on the linear regression equation (milk alcohol level = -0.193 X time + 35.1). (R^2=0.999, P<0.05)
- The mean ethanol disappearance rate in milk was 0.193mg per dL per minute, or 116mg per L per hour.
- Alcohol concentrations in blood at 150 minutes post–CSSR consumption (9.8±4.5mg per dL) were below the detection limit and indistinguishable from zero
- The mean blood ethanol disappearance rate was 90mg per L per hour based on the equation (blood alcohol level = -0.15 X time + 31.9). (R^2=0.994, P<0.05)
- Time to peak milk alcohol levels varied among subjects; average peak time for milk alcohol was 31.7±12.7 minutes post-exposure
- The time to peak blood alcohol levels varied among subjects. Average peak time for blood alcohol was 23.5±7.6 minutes, statistically faster than that in milk (P<0.05)
- Mean maximal milk alcohol concentration in this study was 31.6±10.3mg per dL, and not statistically significantly different (P>0.05) from the mean maximal blood alcohol concentration (30.2±5.0mg per dL)
- The AUCm for the 23 subjects were 2,621±924 minutes^3 mg per dL (range, 1,395 to 4,678 minutes^3 mg per dL)
- The correlation coefficients between blood and milk alcohol levels were variable (range, -0.96 to 0.99; median, 0.79; mean, 0.62). Six of the correlation coefficients (subjects one, four, 13, 14, 16, 22) reached significant levels (P<0.05)
- The correlation coefficient between blood and milk alcohol levels based on pooled data from all subjects was 0.769 (P<0.05).

Author Conclusion:

Nursing infants at least three hours after ingesting a diet containing alcohol, could reduce potential health risks.

Reviewer Comments:

- *Small sample size*
- *The results were not controlled for the subjects' age, BMI, etc.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes
Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A

3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes

6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	N/A
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A

8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes